UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ARNOLD W. WEBSTER, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 01-0928 (ESH)**
PACESETTER, INC.	)	
Defendant.	)	

MEMORANDUM OPINION

Plaintiffs Arnold and Irene Webster have brought this products liability suit to recover damages from injuries suffered by Arnold Webster after heart surgery implanting a pacemaker system produced by defendant Pacesetter, Inc. Plaintiffs allege that the atrial lead of the pacemaker system is defective and caused the perforation of the wall of the atrial chamber of Arnold Webster's heart. As a result, plaintiffs have sued alleging strict liability, negligent design, breach of warranty, and fraud and deceit. Defendant now moves for summary judgment arguing that plaintiffs have failed to make a sufficient showing to establish the elements of their claims. As discussed below, the Court concludes, based on the undisputed evidence, that plaintiffs cannot sustain their burden as to any of their claims, and thus, defendant's motion for summary judgment will be granted.[1/]

[1/] Plaintiffs also seek punitive damages and loss of consortium. Since these claims are dependent on plaintiffs' strict liability, negligent design, breach of warranty, and fraud and deceit claims, they must be dismissed as well.

BACKGROUND

Plaintiff Arnold Webster had a history of heart trouble described as sinoatrial node dysfunction. On July 24, 1998, to stabilize his heart, Arnold Webster underwent an operation to implant a cardiac pacing system, consisting of three components: the TRILOGY DR+ Implantable Pulse Generator, model 2360L; a TENDRIL DX Permanent Pacemaker Electrode, Atrial Lead, model 1388TC; and a Passive PLUS DX Permanent Pacemaker Electrode, Ventricular Lead, model 1346T. (Compl. ¶ 8.) All three components -- the pacemaker and the two leads -- were manufactured by defendant Pacesetter, Inc., a St. Jude Medical Company. (*Id*. ¶ 9.) After a post-surgery diagnostic examination indicating that there were no procedural complications, plaintiff was discharged from Washington Hospital Center in Washington, D.C. (*Id*. ¶¶ 10-12.)

On August 5, 1998, plaintiff became weak and dizzy while riding in a car. He was rushed to an emergency room at the Lady of Lourdes Medical Center in Camden, New Jersey. (*Id*. ¶¶ 13-14.) After review of a CAT scan and echocardiogram, plaintiff's doctors concluded that the atrial lead had perforated the atrial chamber of his heart causing cardiac tamponade (*i.e*., a condition where fluid accumulates in the pericardial sack surrounding the heart). (*Id*. ¶¶ 15-16; Defendant's Motion for Summary Judgment ["Def.'s Mot."] Ex. B, Affidavit of Paul A. Levine [" Levine Aff."] ¶ 17.) The accumulation of the fluid compresses the heart, thereby limiting its ability to fill with blood and compromising its ability to pump blood. (Levine Aff. ¶ 17.) Plaintiff underwent a procedure known as a median sternotomy and the perforation was repaired. On August 13, 1998, plaintiff was discharged from the hospital. (Compl. ¶¶ 17-18.) The original pacemaker and leads have remained implanted and continue to function properly. (Levine Aff. ¶ 18.)

On April 2, 2001, plaintiffs filed suit. The gravamen of their complaint relates solely to the model 1388TC atrial lead. The lead is inserted through a vein and positioned on the inside of the heart.[2/] It carries electrical impulses from the pulse generator to the heart. (Levine Aff. ¶ 6.) Plaintiffs claim that the design of this lead was defective, that defendant failed to provide proper warnings regarding the risks associated with the product, and that these failings caused the perforation and cardiac tamponade suffered by Arnold Webster.

LEGAL ANALYSIS

I. Summary Judgment Standard

Federal Rule of Civil Procedure 56(c) provides that a district court shall grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is (1) no genuine issue as to any material fact and that (2) the moving party is entitled to judgment as a matter of law." *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In considering a motion for summary judgment, the "evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255; *see also Washington Post Co. v. United States Dep't of Health and Human Servs.*, 865 F.2d 320, 325 (D.C. Cir. 1989). However, "the plain language of 56(c), mandates the entry of summary judgment, after an adequate time for discovery, against a party who fails to make a

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[2/] The model 1388T atrial lead is an active fixation lead (as opposed to a passive fixation) that is affixed to the wall of the heart by rotating a fixation helix, a small, corkscrew-shaped component, so that it is screwed into the heart muscle. (*See* Def.'s Reply at 5 n.10.)

showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp v. Cotrett*, 477 U.S. 317, 322 (1986). "A sufficient showing exists when the evidence is such that a reasonable jury could return a verdict for the nonmovant." *Anderson*, 477 U.S. at 248.

II. Strict Liability Claim

The District of Columbia recognizes a cause of action for strict liability in tort based on the principles of the Restatement (Second) of Torts § 402A. *Hull v. Eaton Corporation*, 825 F.2d 448, 454 (D.C. Cir. 1987). "To prevail on a claim for strict liability in tort under § 402A, a plaintiff must prove that: '(1) the seller was engaged in the business of selling the product that caused the harm; (2) the product was sold in a defective condition unreasonably dangerous to the consumer or user; (3) the product was one which the seller expected to and did reach the plaintiff consumer or user without any substantial change from the condition in which it was sold; and (4) the defect was a direct and proximate cause of the plaintiffs injuries.'" *Word v. Potomac Elec. Power Co.*, 742 A.2d 452, 459-60 (D.C. 1999) (quoting *Warner Fruehauf Trailer Co. v. Boston*, 654 A.2d 1272, 1274 (D.C. 1995)). A product may be found defective under section 402(a) "in any of three ways: (1) by defective design, (2) by defective manufacture, or (3) by failure of the producer or assembler to warn adequately of a risk related to the way the product was designed." *MacPherson v. Searle and Co*., 775 F. Supp. 417, 422 (D.D.C. 1991) (citing W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* Sect. 99, at 695 (5th ed. 1984)); Restatement (Second) of Torts § 402A cmt. k (1965)). In this case, plaintiffs claim both defective design and inadequate warnings.

A. Design Defect

With respect to the requirement that the product be sold in a defective and unreasonably dangerous condition, most jurisdictions, including the District of Columbia, apply some form of a risk-utility balancing test to establish strict liability in tort. *Warner Fruehauf*, 654 A.2d at 1276. Under this risk-utility analysis, "plaintiff must 'show the risks, costs and benefits of the product in question and alternative designs' and 'that the magnitude of the danger from the product outweighed the costs of avoiding the danger.'" *Id.* (quoting *Hull*, 825 F.2d at 453).

Defendant argues that plaintiffs cannot make the requisite showing to sustain a claim for design defect because they have failed to: (1) identify a defect in the design of the atrial lead; (2) show that the product was unreasonably dangerous; and (3) establish a causal link between the model 1388TC and plaintiffs' injuries. A careful review of plaintiffs' evidence, including the testimony of their two experts -- John Morris and Edward Reese -- demonstrates the merit of defendant's position.

First, having read the reports and testimony of plaintiffs' experts, one is hard-pressed to even paraphrase their theory as to the specific design defect. Edward Reese, who testified regarding the adequacy of the warnings, is not a medical doctor and admitted that he relied on John Morris' opinion that residual torsion can contribute to delayed tamponade. (Plaintiffs' Opposition to Defendant's Motion for Summary Judgment ["Pls.' Opp."] Ex. 16, Deposition of Edward Reese ["Reese Dep."] at 203.)[3/] The second expert, John W. Morris, who was proffered as an expert in metallurgical

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[3/] In their Counter-Statement of Material Facts Genuinely In Dispute ["Counter-Statement"], plaintiffs cite portions of Reese's report and his deposition to support their assertion that the lead was defective and caused Webster's injuries. (*Id*. at 10 n.28.) However, there is nothing in either reference to support any claim that Reese offered an independent opinion identifying the design defect or

engineering, stated that he did "not know of anything that is specifically defective with the atrial lead." (Pls.' Opp. Ex. 14, Deposition of John William Morris, Jr. Sc.D. ["Morris Dep."] at 94-95.) Nonetheless, plaintiffs point to other portions of Morris' deposition and his report where he claimed that Pacesetter's failure to conduct any research into the root causes of perforation and tamponade rendered the product defective (*see* Morris Dep. at 53), and where he opined that perforation was "most likely" caused by "residual torsion" or residual stress left in the device as a result of the implanting physician having "over-torqued" the atrial lead during the implant surgery. (*See, e.g.*, Morris Dep. at 187; Pls.' Opp. Ex. 3, Report of John W. Morris, Jr. Sc.D. ["Morris Report"] at 6.) Despite the claim that residual stress was "the most likely cause" of the perforation, Morris admitted that he did not know whether there was "residual torsion" left in Webster's atrial lead, and significantly, that the supposed link between "residual torsion" and perforation is based on an unproven "sound mechanical hypotheses" that may or may not be true. (Morris Dep. at 55-56, 73-74.) But even if this theory about "residual torsion" could be validated, which is dubious at best,[4/] Morris has failed to identify the design defect that resulted in the supposed existence of "residual torsion." Obviously, one cannot presuppose the existence of a defect solely on the basis that unintended or undesirable results have occurred. *See Beetler v. Sales Affiliates,* 431 F.2d 651 (7th Cir. 1970) ("theory of . . . strict liability does not impose upon a manufacturer liability for all harm resulting from his product . . . . the product must be

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explaining what caused plaintiffs' injuries.

[4/] By separate motions, defendant has challenged the testimony of plaintiffs' two experts on the grounds that their testimony does not satisfy the standards required by *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Given the Court's disposition of defendant's summary judgment motion, it need not address these *Daubert* challenges.

shown to be defective . . . [and] the defect must render the product unreasonably dangerous."). Moreover, Morris fails to provide any basis for concluding that the lead at issue here is any more likely to result in delayed perforation and tamponade than another pacemaker lead. In fact, just the opposite is demonstrated by the record which indicates, without contradiction, that perforation and cardiac tamponade (including delayed perforation and tamponade) are well-known risks associated with the surgical implantation of *all* pacemaker leads. (See, e.g., Pacesetter's Statement of Material Facts ["Def.'s Facts"] ¶¶ 8-10; Morris Dep. at 70 (admitting that delayed perforation and tamponade occur with a variety of different devices, including active fixation leads, passive fixation leads and catheters); Morris Dep. at 48 (admitting that he does not know whether the design of the 1388TC lead presents any greater risk than any other available pacemaker leads).)[5/]

Second, plaintiffs' risk-utility analysis is fundamentally flawed for a variety of reasons. In their Opposition, plaintiffs claim that the "risk posed by the 1388TC atrial lead far outweighs the utility it provided" since the lead "pose[s]" a "severe danger." (Pls.' Opp. at 31.) Without even addressing the utility factor, plaintiffs make a claim of danger based on "uncontroverted evidence." (*Id*.) This evidence is simply not there. First, plaintiffs base their claim on defendant's technical manual which they claim shows a death rate of one percent due to perforation or tamponade during clinical trials. (*Id*. at 32.) A review of this manual reveals no such information, but rather, the manual says that "[a] total of 10 patients died during the course of [the] clinical trial [of the lead at issue]. None of these deaths were

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[5/] As discussed more fully *infra* at 11-13, plaintiffs attempt in vain to minimize the importance of this medical knowledge by positing that delayed perforation and tamponade are distinguishable from perforation and tamponade that occurs at the time of surgery.

deemed lead related." (Pls.' Opp. Ex. 6.)[6/] To make matters worse, plaintiffs then engage in fanciful extrapolation based on their factually inaccurate premise. (*See* Pls.' Opp. at 19.) From the fact that defendant manufactured and sold tens of thousands of the 1388TC leads during a two-year period, plaintiffs posit that a one percent death rate in the clinical trials means that "for every 10,000 units sold, 100 patients have died due to perforation and tamponade" and then, again without any factual support, plaintiffs claim that "a substantial number of these deaths can be attributed to delayed perforation." (*Id*.) It is thus clear that plaintiffs' claim as to danger based on death rates from perforation and tamponade is totally devoid of any factual foundation.

Similarly, plaintiffs point to "several incidents of delayed tamponade similar to those suffered by Mr. Webster" to bolster their risk-utility analysis. (Pls.' Opp. at 32.) Even plaintiffs' claim of similarity is highly suspect since at least one of the cases did not involve delayed tamponade (Pls.' Opp. Ex. 7); only one of the three incidents involved a 1388TC atrial lead (*id*. Ex. 7) (the other two involved the model 1338T (*id*. Exs. 10 and 8)); and the one incident that involved the 1388TC required removal of the lead and subsequent analysis of the lead indicated that its helix was "clogged with dry body fluid/tissue preventing it from retracting" (*id*. Ex. 7), which was certainly not plaintiff's situation. Finally, these three cases, even if they are arguably similar, hardly demonstrate "severe danger" in light of the tens of thousands of 1388TC leads that have been manufactured and sold,[7/] and the fact that even

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[6/] In fact, is clear from the manual that of some 179 atrial leads that were implanted, there was only one episode of cardiac tamponade. (*See* Pls.' Opp. Ex. 6 at 4.)

[7/] Jonathan Morris, the Manager of Product Analysis and Reliability at St. Jude Medical, testified that during his two-year employment, ending in July 2001, there were tens of thousands of 1388TC leads manufactured and sold. (Pls.' Opp. Ex. 15, Deposition of Jonathan Morris at 51-52.)

plaintiffs' expert agrees that "the great majority of people who have the Pacesetter model 1388 leads implanted in them do not experience any sort of complication or adverse event" and "enjoy . . . the benefit . . . without any particular complication or adverse effect." (Morris Dep. at 185.)

Further, plaintiffs provide no evidence that there is a safer, alternative lead design that could have been used. They merely state that an alternative lead was available, citing a single example of a physician who replaced an active fixation model 1388TC lead with a passive J lead. (Pls.' Opp. at 36.) But, identifying an alternative design is not enough to suggest that the alternative is safer. *Cf*. *Westinghouse Elec. Corp. v. Nutt*, 407 A.2d 606, 611 (D.C. 1979) ("Evidence of a design alternative, by itself, is not sufficient to impose liability on the manufacturer.") Plaintiffs must show that the passive lead is safer, which they cannot do since the unrebutted evidence indicates that it is less preferable than an active fixation lead. For instance, Mr. Webster's physician, Dr. Brian Lewis, testified that he prefers active fixation leads, like the 1388TC, for implantation in the heart's atrial chamber because the passive fixation lead "tends to dislodge very easily" and during his cardiology arrhythmia training, it was "highly recommended that we avoid using [the passive J lead]." (Pls.' Opp. Ex. 21, Deposition of Brian Marc Lewis, M.D. ["Lewis Dep."] at 41-43; s*ee also* Morris Dep. at 70 (acknowledging that delayed perforation and tamponade occur with passive fixation leads).)[8/] In addition, defendants cite a myriad of professional scholarly reports recommending the use of active rather than passive fixation leads in many circumstances. (*See* Def.'s Reply at 7 n.12.)

[8/] Plaintiffs' expert also admits that he does not know whether the design of the 1388TC lead presents any greater risk than any other potential design of a surgically-implantable pacemaker that is available on the market. (Morris. Dep. at 48.)

In sum, plaintiffs have failed to sustain their burden under the risk-utility balancing test: they have not proven the risks associated with the product; they have not provided any information about the cost of avoiding any supposed danger; they never address the benefits of the product; and finally, as to the possibility of an alternative design (*i.e*., the passive J lead), plaintiffs ignore all evidence indicating that it is less preferable than an active fixation lead. *See Hull*, 825 F.2d at 455 ("[E]vidence that one alternative design was technically feasible, and perhaps safer, proves nothing with regard to the actual risk of the chosen design, nor the relative utilities of the alternative designs, nor the cost involved in adopting one design over the other."); *Westinghouse Elec. Corp.*, 407 A.2d at 611 ("It is one thing to show that the defendant might have designed a safer product; quite another to show that the product he did design was unreasonably dangerous.").

Third, with respect to the requirement of causation, plaintiffs' evidence that the defect caused the injuries is insufficient to create a genuine issue of fact. Obviously, having failed to identify a defect in the model 1388TC lead, it necessarily follows that they cannot prove that a defect was a proximate cause of plaintiffs' injuries. *See McFarlane v. Caterpillar, Inc*., 1990 WL 431004, at *5 (D.D.C. July 27, 1990) ("since plaintiffs presented no evidence of defect, it follows that they also presented no evidence of proximate cause.") Moreover, even if they could identify a defect, they have failed to proffer evidence from an expert who can testify to a reasonable degree of certainty that the defect more likely than not caused the injuries. *Clifford v. United States*, 532 A.2d 628, 640 n.10 (D.C. 1987) ("expert must be able to state opinion based on a reasonable degree of medical certainty" to establish causation in a negligence suit). Instead, Morris admitted that he "d[id] not know the probable cause" of the injuries (Morris Dep. at 29), but only that there "may" be a relationship between "residual torsion" in

the lead and the perforation and tamponade (*id*.), and that his opinion is based on "sound mechanical hypotheses" that may or may not be true, for whether residual torsion may be important to delayed perforation cannot be known without further investigation. (*Id*. at 56.) *See Meister v. Medical Engineering Corp*., 267 F.3d 1123, 1125-27 (D.C. Cir. 2001) (rejecting expert causation testimony based on hypotheses in case reports that had not been evaluated or verified).

Regrettably for plaintiffs, Morris conceded that: he has not tested his hypothesis (Morris Dep. at 56-57); there is no evidence that there was in fact residual tension; he has no basis for knowing whether there was any residual tension in the lead at the time of the implant procedure; and he is unaware of any indicia of residual torque (*i.e*., looping figure 8 twists, or kinking) in any of plaintiff's medical records. (Morris Dep. at 74-76).[9/] Therefore, plaintiffs have failed to provide sufficient support for their causation theory.

B. Warning Defect

Similarly, plaintiffs have not alleged facts sufficient to establish that the 1388TC atrial lead is defective based on defendant's failure to provide adequate warnings of its risks. There is no dispute that perforation and tamponade are known risks of pacemaker surgery. (Def.'s Facts ¶ 8.) "Perforation is a known, expected, infrequent complication of the procedure." (Lewis Dep. at 104; *see also* Levine Aff. ¶¶ 7-14 (summarizing supporting authority).) Notice of the risks of tamponade and

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[9/] In juxtaposition, Webster's implanting surgeon, Dr. Brian Lewis, attests, without dispute, that (1) he did not "over-torque" the lead during surgery, (2) neither fluoroscopy during the procedure nor any post-implant x-rays revealed any signs of looping, kinking, figure eights or any other indicia of "residual torsion" in the lead, and, (3) he is unaware of any basis for a conclusion that any "residual torsion" was left in the 1388TC lead upon completion of the surgery. (Def.'s Mot. Ex. C, Declaration of Brian M. Lewis, M.D. ["Lewis Decl."] ¶¶ 12, 16.)

perforation is expressly included in the manual for the 1388TC atrial lead. (Pls.' Opp. Ex. 6 at 2-3.) Plaintiffs, however, argue that the references to cardiac tamponade and perforation contained in the technical manual are inadequate because the manual does not address the risk or causes of *delayed* tamponade or warn that residual torsion may cause tamponade and perforation.

The adequacy of the warnings that accompany a medical device must be assessed from the perspective of the physician using the device. *See Mampe v. Ayerst Laboratories*, 548 A.2d 798, 802 n.6 (D.C. 1988) ("When the purchase of the product is recommended or prescribed 'by an intermediary who is a professional, the adequacy of the instructions must be judged in relationship to that professional.'") (citation omitted). Here, the implanting physician's testimony indicates that the warnings that accompanied the 1388TC atrial lead were adequate. Mr. Webster's physician testified that "all perforations are part of a well-known small risk of complications that the patients and the doctors speak of before surgery" (Lewis Dep. at 55), and that additional warnings in the technical manual would not have affected his decision to use the 1388TC atrial lead. (*Id*. at 103-04.) He states: "My decision to implant the 1388TC lead in Mr. Webster would not have been affected in any way by the inclusion in the 1388TC technical manual of any additional explanations regarding the known risks of delayed perforation and tamponade." (Lewis Decl. ¶ 23.)

Lewis also testified that he understood the warnings in the technical manual "to encompass the risks of delayed perforation and tamponade which refer to the risks that perforation and tamponade can occur at some point after implant." (Lewis Dep. at 100.) Similarly, the physician that repaired Mr. Webster's perforation and relieved the tamponade, testified that perforation and tamponade are well-known risks associated with the surgical implantation of pacemaker leads regardless of whether they

occur at the point of an implant or later, and that the remedial procedure would be the same regardless of when the tamponade occurred. (Pls.' Opp. Ex. 17, Deposition of Dr. John Santasprit ["Santasprit Dep."] at 25-26.) Such testimony indicates that the absence of a specific warning regarding *delayed* perforation and tamponade cannot be the basis of a claim that the 1388TC lead was inadequately labeled.

Despite Dr. Lewis' testimony that the warnings were adequate since he understood the risks of delayed perforation and tamponade, plaintiffs insist that "delayed tamponade is not a widely known risk" and that "delayed perforation is not a complication widely recognized in the medical literature." (Counter-Statement ¶¶ 8, 9). In making this assertion, plaintiffs refer only to the testimony of Dr. Paul Levine, Medical Director of St. Jude Medical. However, the cited deposition pages (*see* Levine Dep. at 23, 29) do not support plaintiffs' position. In his testimony, Dr. Levine merely confirms that perforations usually occur at the time of implantation and that the medical literature notes the fact of perforations occurring during the implant process. *Id*. Dr. Levine, however, does not address the extent to which *delayed* perforation and tamponade are recognized as risks by the medical community. He does, however, address this in his affidavit, which plaintiffs conveniently ignore. There, he avers that "[w]hile myocardial perforations usually occur at the time of implantation, there are reports of late perforations occurring days or weeks following implantation." (Levine Aff. ¶ 20.) In addition, plaintiffs disregard the testimony of two other doctors -- Charles Love and John Santasprit -- who have testified that delayed tamponade and perforation are well-known risks in the medical community. (Santasprit Dep. at 25-26; Pls.' Opp. Ex. 19, Deposition of Charles J. Love, M.D. ["Love Dep."] at 17.)

In short, plaintiffs cannot fault defendant for failing to warn specifically of delayed perforation

and tamponade. Such risks were known to the treating physician, who testified that he would not have done anything differently even if the word "delayed" had been used, and such risks are also recognized and known within the medical community. There can thus be no argument that the warnings were defective or that any alleged inadequacies in the warnings were a proximate cause of plaintiffs' injuries. *See Mampe*, 548 A.2d at 802; *Dyson v. Pharmacia*, 129 F. Supp.2d 19, 21 (D.D.C. 2001); *Dyson v. Winfield*, 113 F. Supp.2d 35, 41 (D.D.C. 2000).

Plaintiffs also attempt to undercut Dr. Lewis' testimony by arguing, without any legal support, that his testimony is "irrelevant" because "what matters is the conduct of *reasonable* healthcare providers when they have the knowledge of the risks that were known or should have been known." (Pls.' Opp. at 38.)[10/] Of course, the relevant test does not speak of the "reasonable health care provider," but focuses only on the "prescribing physician." *Mampe*, 548 A.2d at 802; *Dyson*, 129 F. Supp.2d at 21.

[10/] Plaintiffs offer no expert testimony regarding what a reasonable healthcare provider needed to know that was not contained in the labeling or not known by the medical community. Plaintiffs' only expert on this issue, Edward Reese, is not a doctor and he declined to offer any opinion as to the adequacy of the warnings and labeling from the perspective of a "reasonable health care provider," nor did he refute the testimony of the prescribing physician. (*See, e.g.*, Reese Dep. at 195-96.) *See Williard v. Park Industries*, 69 F. Supp. 2d 268, 272 (D.N.H. 1999) (expert testimony required in strict liability case challenging adequacy of warnings where "the matter to be determined is . . . beyond the ken of the average layman"); *Hill v. Squibb and Sons*, 592 P.2d 1383 (Mont. 1979) (expert evidence required to determine adequacy of a warning directed to physicians); *Northern Trust Co. v. Upjohn*, 572 N.E.2d 1030, 1035-36 (Ill. App. 3d 1991) (expert testimony necessary where manufacturer's liability for prescription drug is based on its failure to provide adequate warning); *Dion v. Graduate Hosp. of Univ. of Pa.*, 1986 WL 501497 (Pa. Com. Pl. Feb. 28, 1986) ("since the warning is directed to physicians, only they or others with similar education and experience . . . would be qualified to determine whether or not the warning was adequate").

Second, plaintiffs cannot bootstrap their arguments regarding defendant's alleged failure to report and to investigate adverse incidents to the FDA into a defective warning case. As an initial matter, plaintiffs are precluded from arguing that defendant's alleged "failure to adhere to the FDA regulations on recordkeeping, labeling, design validation and establishment and maintenance of complaint file" (Pls.' Opp. at 50) supports a defective warning case, since such claims are preempted by the Federal Food, Drug and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 301, under the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 348 (2001) ("[P]laintiffs' state-law fraud on the FDA claims conflict with, and are therefore impliedly preempted by, federal law.")

In addition to this legal deficiency, several of plaintiffs' key factual assertions are flatly inconsistent with the uncontroverted evidence. For instance, plaintiffs allege that defendant improperly "dispens[ed] with its obligation to apprise the FDA" that it would distribute the 1388TC lead with only the clip-on tool rather than both the clip-on tool and the fixation tool that had been included with the predecessor model 1388T lead. (Pls.' Opp. at 8.) However, the record indicates that the FDA explicitly acknowledged this change. (*See* Pacesetter's Statement of Points and Authorities in Support of Its Motion to Exclude Opinion Testimony of Edward W. Reese Ex. F at 9 ("FDA also acknowledges your marketing of the . . . Model 1388T/C lead, which is identical to the approved Model 1388T, except that it is packaged only with the clip-on accessory.").) Plaintiffs also charge that defendant failed to respond to an FDA inquiry about the causes and circumstances surrounding a death from cardiac tamponade. (Pls.' Opp. at 20 (citing Pls.' Opp. Ex. 1 at 7 ¶ j).) However, the incident referenced did not result in the death of the patient (Pls.' Opp. Ex. 10), and defendant did, in

fact, respond to the FDA inquiry. (*See* Def.'s Reply Ex. A.) Finally, plaintiffs suggest that defendant misclassified incidents of tamponade as "not reportable" rather than as "serious injury." (Pls. Opp. at 21.) Plaintiffs, however, cite only one example of this alleged problem and the report cited clearly classifies the incident as a serious injury. (*See* Pls.' Opp. Ex. 7 at 03962.)

Nor can plaintiffs create an issue of fact regarding their defective warning claim by speculating that *if* the FDA had known of the delayed perforation and tamponade incidents during the clinical trials and *if* defendant had investigated all the adverse incidents, the FDA would have either recalled the lead or placed it on alert, and therefore, Dr. Lewis would not have implanted it in plaintiff's heart. (Pls.' Opp. at 50.) For, as noted, what was told to the FDA cannot support a tort claim, and more importantly, plaintiffs' approach would be nothing more than an invitation for the jury to speculate about what both the FDA and Dr. Lewis might do if the facts were different.

Finally, plaintiffs try to create an issue of fact regarding the adequacy of the warnings by making much of the fact that the 1388TC technical manual does not contain the instruction referencing "residual torque" that was included in the manual for the earlier 1388T model. (*See* Pls.' Opp. at 10-12.) The instruction for the 1388T lead stated:

> When withdrawing the stylet, look for any signs of residual torque (looping, figure 8 twists in the lead body, etc.). It is important to relieve this tension by turning the fixation tool counterclockwise until the tension dissipates.

(Pls.' Opp. Ex. 5 at 20.) Of course, given the testimony of the treating physician, Dr. Lewis, this change in warnings is irrelevant, since plaintiffs cannot show that the warnings that accompanied the 1388TC were inadequate from the perspective of the treating physician. Moreover, as noted, the FDA

was advised of this change, and the FDA acknowledged that the two models were "identical" except that the latter 1388TC lead was marketed with only a clip-on tool accessory, while the prior model (the 1388T) had both a clip-on and fixation tool.[11/] Finally, any nefarious inferences that plaintiffs attempt to draw from the deletion of this instruction cannot, without more, support a defective warning claim given the fact that the deleted instruction refers explicitly only to the fixation tool and that tool was not distributed with the 1388TC model. (*See* Def.'s Reply at 13.) Morever, as explained by Dr. Lewis, with respect to the clip-on tool that was distributed with the 1388TC, there is no need to turn the clip-on tool counter-clockwise to relieve tension in the lead because tension is automatically released when the clip-on tool is removed. (Lewis Dep. at 81-82.)

In sum, plaintiffs have failed to create any material issues of fact with respect to their strict liability claim, for their evidence does not show that the product was defectively designed or that the warnings were inadequate from the perspective of the treating physician. They have failed to show that the product was unreasonably dangerous, and there is insufficient evidence that any alleged defect or lack of warnings was a proximate cause of plaintiffs' injuries. Therefore, Count I must be dismissed.

III. Negligent Design

To prove that Arnold Webster's injuries were the result of defendant's negligence, plaintiffs must make a sufficient showing that defendant did not exercise reasonable care in adopting a safe

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[11/] It is also noteworthy that the FDA approved the earlier model 1388T with both the fixation tool and the clip-on tool. (Supplement to Pacesetter, Inc.'s Motion for Summary Judgment Ex. 3, Affidavit of Lydia Telep ¶ 16.)

design for the lead and that the failure to exercise reasonable care caused plaintiffs' injuries. *Pappas v. Fort Motor Co*., 7 F. Supp. 2d 22, 24-25 (D.D.C. 1998). Like the risk-utility test applied in a strict liability claim, determining what constitutes reasonable care "involves a balancing of the likelihood of harm, and the gravity of the harm if it happens, against the burden of precaution which would be effective to avoid the harm." *Id.*

The same factors are considered in both a negligent design case and a strict liability case. However, in a negligence case the focus is on the manufacturer's conduct and not on the product itself. *Warner Fruehauf*, 654 A.2d at 1277 n.13. *See also Hull*, 825 F.2d at 453-54. Here, both parties rely solely on the same arguments they presented with respect to the strict liability claim. Based on these arguments, there is no evidence that defendant engaged in unreasonable conduct in placing the atrial lead on the market, that a safer alternative design could have been developed, or that any alleged unreasonable conduct was the cause of Mr. Webster's injuries. Thus, the application of the risk-utility test to the manufacturer's conduct produces the same result as its application to the product, and summary judgment must be granted with respect to plaintiffs' negligence claim.

IV. Breach of Warranty

"[T]he difference between strict liability in tort and implied warranty, if any, are conceptual." *Wainwright v. Washington Metro. Area Transit Auth.*, 903 F. Supp. 133, 139 (D.D.C. 1995). Again, plaintiffs rely solely on their strict liability claim to support their breach of implied warranty

claim.[12/] (Pls.' Opp. at 52.) Thus, like their strict liability claim, plaintiffs' implied warranty claim cannot survive summary judgment. *See Dyson*, 113 F. Supp. 2d at 42 ("'where there are no issues unique to [the] warranty [claim],' the warranty claim effectively merges with the strict liability claim" (quoting *Wainwright*, 903 F. Supp. at 139)). Moreover, the claim must be dismissed because "a breach of warranty claim is not actionable in coordination with a products liability claim." *Dyson*, 113 F. Supp. 2d at 42.

V. Fraud and Deceit

Plaintiffs' fraud and deceit claims are equally unfounded. In the District of Columbia, a fraud claim requires "(1) a false representation, (2) in reference to a material fact, (3) . . . with knowledge of falsity, (4) . . . intent to deceive, and (5) action [ ] taken in reliance upon the representation." *Dyson*, 113 F. Supp. 2d at 43 (citing *Bennett v. Kiggins*, 377 A.2d 57, 59 (D.C. 1977)). The last element of a fraud claim is "analogous to the causation element in tort." *Id*. The Court has already determined that plaintiffs cannot establish the causation element of their strict liability and negligence claims because they did not provide any evidence that warning of the risk of delayed tamponade or residual torsion would have affected the treatment of Mr. Webster in any way. Thus, they cannot establish that any action was taken in reliance on any alleged false representation. Further, plaintiffs do not provide any

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[12/] Plaintiffs' breach of warranty claim alleges breach of both express and implied warranties. (Compl. ¶¶ 34-35.) However, plaintiffs essentially concede their express warranty claim by stating that "[w]ith respect to the warranty issue, it is possible that Pacesetter disclaimed any express warranty." (Counter-Statement ¶ 10.)

support for their claim that defendant "had a duty to warn physicians about possibilities of delayed tamponade," or residual torsion -- the basis of the alleged false misrepresentation. (Pls.' Opp. at 54.)

Finally, to the extent that plaintiffs base their fraud claim on defendant's alleged failure to provide the FDA with information required by the MDA (*id*.), the claim is precluded by the Supreme Court's ruling in *Buckman*, 531 U.S. at 349 (private litigants preempted from filing suit against a manufacturer for noncompliance with the MDA). Plaintiffs argue that if defendant had adhered to MDA requirements regarding record-keeping, adverse incident reporting, investigation, monitoring and complaint file maintenance, the 1388TC lead would have been recalled or placed on alert notice and plaintiff would not have been injured. (*See* Pls.' Opp. at 54.) This is precisely the type of claim barred by the Supreme Court. *Buckman*, 531 U.S. at 342. Consequently, plaintiffs have failed to make a showing sufficient to establish the elements of their fraud and deceit claim.

CONCLUSION

In sum, plaintiffs have not established any of their claims, and therefore, defendant's motion for summary judgment is granted. A separate Order accompanies this Memorandum Opinion.

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ELLEN SEGAL HUVELLE
United States District Judge

Dated:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ARNOLD W. WEBSTER, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 01-0928 (ESH)**
PACESETTER, INC.	)	
Defendant.	)	

ORDER

This matter is before the Court on Defendant Pacesetter, Inc.'s Motion for Summary Judgment [65-1]. Based on the pleadings, the entire record, and the relevant case law, and for the reasons set forth in the Memorandum Opinion accompanying this Order, it is hereby

ORDERED that defendant's motion for summary judgment is **GRANTED**; and it is

FURTHER ORDERED that all other pending motions in this case are **DENIED AS MOOT**; and it is

FURTHER ORDERED the Complaint is **DISMISSED WITH PREJUDICE.**

SO ORDERED.

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ELLEN SEGAL HUVELLE
United States District Judge

Dated:

cc: Magistrate Judge Alan Kay